**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| IVAX PHARMACEUTICALS, INC., | : | |
| Plaintiff, | : | CIVIL ACTION NO. 08-2165 (JAP) |
| v. | : | |
| ASTRAZENECA AB, et al., | : | **OPINION** |
| Defendants. | : | |

PISANO, District Judge.

Presently before the Court is a motion to dismiss pursuant to Federal Rule of Civil 12(b)(1) brought by Defendants AstraZeneca AB ("AstraZeneca") and Merck & Co., Inc. ("Merck") (collectively, "Defendants"). Alternatively, Defendants seek the Court to stay the action brought by Plaintiff Ivax Pharmaceuticals, Inc. ("Plaintiff"). Plaintiff opposes the motion. For the reasons set forth herein, the Court grants in part and denies in part Defendants' motion to dismiss, and grants the motion to stay the action pending resolution of a related action between the parties.

## I. BACKGROUND

This cause of action is one seeking a declaratory judgment of patent noninfringement and patent invalidity brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, commonly referred to as the "Hatch-Waxman Act," 21 U.S.C. §

355(j)(5)(C). Plaintiff is a generic drug manufacturer and seeks to enter the market for 20 milligrams ("mg") and 40 mg capsules of esomeprazole magnesium. Defendants, also drug manufacturers, market NEXIUM® esomeprazole magnesium 20 mg and 40 mg capsules. To that end, AstraZeneca owns a New Drug Application ("NDA") Number 21-153, approved by the United States Food and Drug Administration ("FDA") and covering those capsule forms of esomeprazole magnesium. Defendants also own ten patents relating to the manufacture, use, or sale of esomeprazole magnesium capsules; United States Patent Numbers: 5,690,960 ("the '960 Patent"); 5,900,424 ("the '424 Patent"); 6,147,103 ("the '103 Patent"); 6,166,213 ("the '213 Patent"); 6,191,148 ("the '148 Patent"); 5,714,504 ("the '504 Patent"); 5,877,192 ("the '192 Patent"); 6,875,872 ("the '872 Patent"); 6,428,810 ("the '810 Patent"); and 6,369,085 ("the '085 Patent"). The FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(i), listed these patents in the publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

On November 23, 2005, Plaintiff filed with the FDA Abbreviated New Drug Application ("ANDA") Number 78-003, seeking approval to market generic forms of NEXIUM® 20 mg and 40 mg esomeprazole magnesium capsules. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Plaintiff filed "Paragraph IV" certifications as to the ten patents listed in the Orange Book, placing Defendants on notice that Plaintiff believed those patents to be invalid or its attempted use of the esomeprazole magnesium capsules would not infringe those patents. Plaintiff also provided Defendants with an offer of confidential access to the ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) and (III). Plaintiff, however, was not the first filer of an ANDA

for esomeprazole capsules that included Paragraph IV certifications as to the listed patents.[1]

On March 8, 2006, AstraZeneca and its related entities invoked their statutory right to sue under the Hatch-Waxman Act, and brought a cause of action for patent infringement against Plaintiff. *AstraZeneca AB v. Ivax Corp.*, No. 06-1057 (D.N.J.), consolidated with *AstraZeneca AB v. Ranbaxy Pharm., Inc.*, No. 05-5553 (D.N.J.). In that complaint, AstraZeneca alleged that Plaintiff's ANDA product infringed five of AstraZeneca's patents: the '504, '192, '872, '810, and '085 Patents. AstraZeneca, however, did not assert any claims relating to the '960, '424, '103, '213, or '148 Patents.

On April 30, 2008, Plaintiff filed the present action under 21 U.S.C. § 355(j)(5)(C)(i). Plaintiff seeks declaratory judgments that state that its use of the generic form of the 20 mg and 40 mg esomeprazole magnesium capsules does not infringe the five patents not subject to the action brought by AstraZeneca: those are, the '960, '424, '103, '213, and '148 Patents. In addition, Plaintiff seeks declaratory judgments that the '960, '424, '103, '213, and '148 Patents are invalid under 35 U.S.C. § 101 *et seq.*

Presently, Defendants move to dismiss Plaintiff's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1). Defendants argue that the Court does not have subject matter jurisdiction over the action because the Complaint does not present an actual case or controversy pursuant to Article III, Section 2 of the United States Constitution. Defendants assert that there is no real immediacy that either AstraZeneca or Merck will bring suit as to the five patents at

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[1] Plaintiff proffers that the first ANDA was filed by Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy Inc. (collectively, "Ranbaxy"). On November 21, 2005, AstraZeneca, along with its entities, filed an action of patent infringement against Ranbaxy relating to Ranbaxy's ANDA Number 77-830. *AstraZeneca AB v. Ranbaxy Pharm., Inc.*, 05-5553 (D.N.J.).

issue in this action. Defendants further point out that Merck provided Plaintiff with irrevocable covenants not to sue as to the three patents owned by Merck: the '103, '213, and '148 Patents. Alternatively, Defendants seek the Court to stay the action pending resolution of AstraZeneca's infringement complaint against Plaintiff. According to Defendants, if AstraZeneca succeeds on the merits of that action, then the FDA will not approve Plaintiff's ANDA until after the expiration of the relevant patents which is to occur in the years 2014 and 2015. Thereby, the result of that action may effect the justiciability or merits of the present action.

Plaintiff opposes the motion. Plaintiff contends that a sufficient controversy exists because it faces "uncertainty and great potential risk if" Defendants assert claims of patent infringement of the five patents after Plaintiff begins marketing its generic form of the drug. In addition, Plaintiff proffers that the covenants not to sue do not extinguish that risk. Finally, Plaintiff contends that a stay of this action is not warranted.

## II. DISCUSSION

### A. Motion to Dismiss

#### 1. *Standard of Review under Federal Rule of Civil Procedure 12(b)(1)*

Federal Rule of Civil Procedure 12(b)(1) allows a party to move for dismissal of claims based on a lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a court attaches "no presumptive truthfulness" to the allegations of the non-moving party, and "the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). When reviewing a factual challenge to subject matter jurisdiction—such as the challenge

asserted here—a court "may consider evidence outside the pleadings." *Gould Elec. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). *See Med. Soc'y of N.J. v. Herr*, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) (distinguishing factual challenge from facial challenge by stating that "factual 12(b)(1) motion . . . calls into question the essential facts underlying a claim of subject matter jurisdiction"). The plaintiff bears the burden of establishing that jurisdiction exists. *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006); *Med. Soc'y of N.J.*, *supra*, 191 F. Supp. 2d at 578.

**2. *Analysis***

Here, Defendants argue that the Court lacks subject matter jurisdiction over Plaintiff's declaratory judgment action because it does not invoke an actual case or controversy. This motion, thus, calls into question whether Article III justiciability exists over this patent dispute.

A justiciable declaratory judgment action, in the context of an alleged patent infringement claim, occurs where "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, __, 127 S. Ct. 764, 771 (2007) (internal quotation marks and footnote omitted). In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corporation*, 482 F.3d 1330 (Fed. Cir. 2007), the United States Court of Appeals for the Federal Circuit held that, "where a generic applicant has challenged a patent by filing an ANDA with a paragraph IV certification and [has] not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable 'case or controversy' under the Constitution." *Teva Pharm.*, *supra*, 482 F.3d at 1343 (internal editing marks omitted).

In that case, the court found that a concrete, present injury existed in an action brought by a generic drug manufacturer against a patent holder for patents listed in the Orange Book that were not raised in a related action of patent infringement brought by the patent holder. *Id.* at 1341. The Federal Circuit found that the "threat of litigation is a present injury creating a justiciable controversy[,]" and emphasized that the patent holder retained the right to sue the plaintiff for those patents, notwithstanding the fact that the holder had not yet exercised that right. *Ibid.*

The *Teva* Court enunciated three circumstances dispositive to establish an actual declaratory judgment controversy as to all the patents subject to Paragraph IV certifications: (1) a patent holder lists patents in the Orange Book; (2) an ANDA applicant files its ANDA certifying the listed patents under Paragraph IV; and (3) the patent holder brings an action against the ANDA applicant on one or more of the patents. *Id.* at 1344. Nevertheless, the court expressed its belief that "the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe." *Id.* at 1343.

One year after *Teva Pharmaceuticals*, however, the Federal Circuit, applying a prior version of the Hatch-Waxman Act, found that a unilateral covenant not to sue provided to an ANDA applicant from a patent holder did not render moot a declaratory judgment action over a patent. *Caraco Pharm. Lab., Ltd. v. Forest Lab., Inc.*, 527 F.3d 1278, 1297 (Fed. Cir. 2008). In *Caraco*, a generic drug manufacturer brought a declaratory judgment action, seeking a declaration that its use of a generic form of escitalopram set forth in an ANDA application did not infringe a patent listed by the defendant in the Orange Book. *Id.* at 1281-82, 1288. Upon

issuance of the *Teva Pharmaceutical* Opinion from the Federal Circuit, the defendant patent holder in *Caraco* provided the plaintiff with a covenant not to sue for infringement of the patent in dispute based on the plaintiff's ANDA. *Id.* at 1289. Due to the existence of the covenant not to sue, the district court dismissed the action for failing to present an Article III case or controversy. *Id.* at 1289-90. The Federal Circuit, however, reversed. *Id.* at 1282.

In conducting its analysis, the Federal Circuit considered whether the covenant not to sue rendered the action moot. *Id.* at 1296. The court noted that the covenant eliminated "any reasonable apprehension of suit" on the patent, and would moot any allegation that a reasonable "threat of suit" effectively excluded the plaintiff from entering the marketplace. *Ibid.* The court further noted that, "in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace." *Ibid.* It also stated that "a covenant not to sue on a patent ensures that the covenant's recipient will not be liable for damages or subject to an injunction for infringement of that patent." *Ibid.* However, rather than simply alleging a threat of suit, the *Caraco* plaintiff, who was not the first Paragraph IV ANDA filer as to the patent in dispute, also alleged that the listing of the patent in the Orange Book prevented the plaintiff from entering the marketplace. *Ibid.*

The Federal Circuit thereby found the present action arose in a "unique" situation created by a previous version of the Hatch-Waxman Act. *Ibid.* The prior version of the Hatch-Waxman Act prevented the plaintiff from entering the marketplace until the issuance of a "final court decision finding the relevant Orange-Book-listed patents invalid and not infringed" because such an order was necessary to trigger the 180-day period of exclusivity granted to the initial ANDA

filer. *Id.* at 1283-84 (citing 21 U.S.C. § 355(j)(5)(B)(iv) (2000)) and 1296.[2] The *Caraco* Court noted that, had the plaintiff been the first Paragraph IV ANDA filer, it would not have to await a court declaration to enter the marketplace. *Id.* at 1283. Finding that, absent a court judgment in respect of the infringement of the patent in dispute, the plaintiff could not obtain FDA approval of its ANDA, the Federal Circuit held that the action presented a case or controversy sufficient for Article III justiciability. *Id.* at 1297.

However, under the current version of the Act, a court's final judgment is no longer required to trigger the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv); *see Caraco*, *supra*, 527 F.3d at 1283 n.2. On December 8, 2003, Congress amended the Hatch-Waxman Act as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. *Id.* at 1283 n.2. The amendments do not apply where a generic drug company filed a Paragraph IV ANDA before December 8, 2003. *Ibid.* In *Caraco*, the initial ANDA filer filed its ANDA in August of 2003, and, for that reason, the Federal Circuit applied the prior version of the Hatch-Waxman Act. *Ibid.* The *Caraco* Court did not discuss if it would reach the same result as to the issue of the covenants not to sue if it had applied the amended version of the Act. Nevertheless, considering that the rationale applied in *Caraco* relied principally on a "unique" situation created by a provision of the Hatch-Waxman Act that no longer exists, the Court finds that *Caraco* does not apply to issues presented under the current version of the Hatch-Waxman Act.

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[2] Under the previous version, the FDA would not approve a subsequent ANDA filer until the expiration of 180 days after the earlier of either: (1) the date of the "first commercial marketing" of the first ANDA filer's generic drug or (2) the date of a court decision holding the patent that is the subject of the Paragraph IV certification to be invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). *See* Erika Lietzan and David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 Food & Drug L.J. 49, 49-50 (2007) (discussing 2003 amendments to 180-day exclusivity period provisions of Hatch-Waxman Act).

Applying those concepts to the present action, the Court finds that Plaintiff presents a concrete case or controversy as to the '960 and '424 Patents, but does not present an actual case or controversy as to the '103, '213, and '148 Patents. As to the '960 and '424 Patents, jurisprudence establishes that an actual case or controversy exists upon the occurrence of three events: (1) a patent holder lists patents in the Orange Book; (2) an ANDA applicant files its ANDA certifying the listed patents under Paragraph IV; and (3) the patent holder brings an action against the ANDA applicant on one or more of the patents. *Teva Pharm.*, *supra*, 482 F.3d at 1344. Those three events have taken place here: Defendants have listed its ten patents relating to the esomeprazole magnesium capsules in the Orange Book, Plaintiff filed Paragraph IV certifications with its ANDA in respect of all ten listed patents, and AstraZeneca has initiated an action against Plaintiff on five of those patents. Yet, AstraZeneca retains the right to sue over the '424 and '960 Patents that are not part of its infringement suit against Plaintiff. Accordingly, Plaintiff faces possible future litigation on those two patents, "thus creating legal injuries sufficient to establish a justiciable controversy." *Merck & Co. v. Apotex, Inc.*, 2007 WL 4082616, *5 (D.N.J. Nov. 15, 2007).

That threat of litigation has been extinguished as to the '103, '213, and '148 Patents owned by Merck by virtue of the covenants not to sue. As a threshold matter, the Court finds that *Caraco* does not apply to this dispute. Both Plaintiff and Ranbaxy, the initial filer of an ANDA relating to the patents in dispute, filed their ANDAs after December 2003, and, thus, the Court must apply the current amended version of the Hatch-Waxman Act. As stated above, the 2003 version of the Hatch-Waxman Act does not invoke the concerns relied upon by the Federal Circuit in *Caraco*. In addition, the Court finds Plaintiff's arguments in respect of the status of

the litigation between AstraZeneca and Ranbaxy to be inapplicable. Applying *Teva Pharmaceuticals*, the Court finds that the issuance of the covenants not to sue provide Plaintiff with sufficient certainty that it does not face a threat of suit as to the '103, '213, or '148 Patents. *Teva Pharm.*, 482 F.3d at 1343. *Accord Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 2007 WL 3014702, *3 (D.N.J. Oct. 11, 2007) (holding that, as to asserted counterclaims,"[p]laintiffs gave [d]efendant a covenant not to sue, and therefore [p]laintiffs' motion to dismiss regarding the patents in the covenant not to sue must be granted").

Accordingly, the Court holds that Plaintiff has established Article III justiciability as to the '424 and '960 Patents, but not as to the '103, '213, and '148 Patents. Moreover, the Court finds that Plaintiff's delay in bringing this action does not divest the Court of subject matter jurisdiction, or otherwise suggest that the Court should exercise its discretion to refrain from adjudicating this declaratory judgment action. Therefore, the Court grants Defendants' motion to dismiss as to Plaintiff's claims relating to the '103, '213, and '148 Patents, but denies Defendants' motion to dismiss as to Plaintiff's claims relating to the '424 and '960 Patents.

**B. Motion to Stay**

Alternatively, Defendants also move to stay proceedings in this matter pending resolution of AstraZeneca's litigation against Plaintiff relating to Plaintiff's ANDA. "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). A grant of a stay of proceedings is within the Court's discretion, and the Court "must weigh competing interests[.]" *Id.* at 254-55. Considering that the resolution of AstraZeneca's claims in its related infringement action could

effect Plaintiff's claims as to the '424 and '960 Patents, and recognizing the complexity of the issues as well as the extensive discovery necessarily invoked by this action, the Court finds that a stay is appropriate. Accordingly, the Court hereby invokes its inherent power to control its docket and stays the present action pending resolution of *AstraZeneca AB v. Ivax Corp.*, No. 06-1057 (D.N.J.), consolidated with *AstraZeneca AB v. Ranbaxy Pharm., Inc.*, No. 05-5553 (D.N.J.).

## III. CONCLUSION

For the reasons expressed above, the Court grants in part Defendants' motion to dismiss Plaintiff's Complaint as to the claims relating to the '103, '213, and '148 Patents, but denies in part the motion as to Plaintiff's claims relating to the '424 and '960 Patents. The Court further grants Defendants' motion to stay the surviving portions of the action, and stays the present action pending resolution of the related patent infringement action. An appropriate Order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: August 28, 2008